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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/482,653	01/13/2000	JOHN A. WELLS	70869-0078	7295
22902	7590	08/02/2002		
CONRAD J. CLARK CLARK & BRODY 1750 K STREET NW SUITE 600 WASHINGTON, DC 20006			EXAMINER COOLEY, CHARLES E	
			ART UNIT 1723	PAPER NUMBER

DATE MAILED: 08/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

TC-13

<b>Office Action Summary</b>	Application No. 09/482,653	Applicant(s) Wells, Deceased et al.
	Examiner Charles Cooley	Art Unit 1723
		
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>		
<b>Period for Reply</b> A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.		
<p><i>[List of conditions for reply period]</i></p>		
<b>Status</b> 1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>15 Jul 2002</u> 2a) <input type="checkbox"/> This action is FINAL.      2b) <input checked="" type="checkbox"/> This action is non-final. 3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.		
<b>Disposition of Claims</b> 4) <input checked="" type="checkbox"/> Claim(s) <u>1-37</u> is/are pending in the application. 4a) Of the above, claim(s) _____ is/are withdrawn from consideration. 5) <input type="checkbox"/> Claim(s) _____ is/are allowed. 6) <input checked="" type="checkbox"/> Claim(s) <u>1-37</u> is/are rejected. 7) <input type="checkbox"/> Claim(s) _____ is/are objected to. 8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.		
<b>Application Papers</b> 9) <input type="checkbox"/> The specification is objected to by the Examiner. 10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.		
<b>Priority under 35 U.S.C. §§ 119 and 120</b> 13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received.		
14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received. 15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
<b>Attachment(s)</b> 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____		

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***Surrender of Patent***

4. The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178. The "Offer to Surrender Patent" filed 01 SEP 2000 is not a proper offer to surrender.

***Reissue Oath/Declaration***

5. The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:

- a. It does not identify the citizenship of each inventor (37 CFR 1.63(a)(3)).
- b. It does not state whether the inventor is a sole or joint inventor of the invention claimed (37 CFR 1.63(a)(3)).
- c. It appears the name of the first inventor is actually --John R. Wells-- rather than "John A. Wells".
- d. Is item (4) of the declaration missing data? (by any amendment on \_\_\_\_\_).

6. Claims 1-37 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the declaration is set forth in the discussion above in this Office action.

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***Drawings***

7. Requirements for drawings in reissue applications are found in 37 CFR 1.174 and MPEP 1413.

***Specification***

8. The abstract is acceptable.
9. The amended title of the invention is acceptable.

***Claim Rejections - 35 U.S.C. § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

11. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily

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## OFFICE ACTION

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 JUL 2002 has been entered.

### ***Assignee***

2. Receipt is acknowledged of a Consent of Assignee and Statement under 37 CFR 3.73(b) filed 29 OCT 2001.

### ***Inventorship***

3. Th requirement for proof of authority of the legal representative for deceased inventor John A. Wells is withdrawn in view of the new rules which no longer requires such proof.

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published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

**12. Claims ~~22, 23, 24, 25, 26, 27, 28, and 29~~ are rejected under 35 U.S.C.**

**§ 102(b) as being anticipated by Raccuglia et al. (USP 3,190,546).**

The patent to Raccuglia et al. discloses a system in Figs. 8-11 comprising a centrifuge 212 with a rotor 214; a walled container 110, 112 (Figs. 8-9) having a first chamber 114 and a second chamber 116; a bridge 166, 162, 141, 140, 168, 164, 153, 152 for transferring fluid between the chambers; a holder assembly (Fig. 11) comprising a pivotally mounted frame 216 attached to the centrifuge rotor 214 for removably receiving the container 110, 112 and for positioning the container in multiple positions as seen in the solid and phantom positions of Figure 10; lid portions 120, 122; and access port 118. Although the adjective "sterile" is not considered a structural limitation as explained below, a primary objective of Raccuglia et al. is the separation of blood which would mandate the container being sterile. Accordingly, sterility is considered to be inherent characteristic of the container in Raccuglia et al.

**13. Claims ~~25-27~~ are rejected under 35 U.S.C. § 102(e) as being anticipated by Li (USP 5,503,284).**

The patent to Li discloses a walled container 12 comprising a first chamber 16, 38 and a second chamber 40; a bridge 34 for transferring fluid between the chambers (Figs. 3-8); a removable lid C; and access port 26.

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*maintain*

**14. Claims 25-27 are rejected under 35 U.S.C. § 102(b) as being anticipated by McFarland (USP 3,642,163).**

The patent to McFarland discloses a walled container (Fig. 1) comprising a first chamber 12 and a second chamber 14; a bridge 32; a removable lid 18; and access port (proximate 22).

**15. Claims 33 and 36 are rejected under 35 U.S.C. § 102(b) as being anticipated by McFarland (USP 3,642,163).**

The patent to McFarland discloses a walled container (Fig. 3) comprising a first chamber 12A and a second chamber 14A; a bridge 62; lid 66; access ports 70; and separation disks 38.

**16. Claims 25-27 are rejected under 35 U.S.C. § 102(b) as being anticipated by Crippa (USP 4,026,433).**

The patent to Crippa discloses a walled container comprising a first chamber 1 and a second chamber 7; a bridge 4 (Fig. 4); a removable lid 10; and access port (proximate 6). Although the adjective "sterile" is not considered a structural limitation as explained below, a primary objective of Crippa is providing a container for holding medical specimens to be analyzed which would mandate the container being sterile. Accordingly, sterility is considered to be inherent characteristic of the container in Crippa.

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*maintain*

**17. Claims 33 and 37 are rejected under 35 U.S.C. § 102(b) as being anticipated by Crippa (USP 4,026,433).**

The patent to Crippa discloses a walled container comprising a first chamber 1 and a second chamber 7; a bridge 4 (Fig. 4); a lid 10; access ports (proximate 3 and 6); the bridge 4 being formed at the tops of the adjacent sidewalls of the chambers (Fig. 4). Although the adjective "sterile" is not considered a structural limitation as explained below, a primary objective of Crippa is providing a container for holding medical specimens to be analyzed which would mandate the container being sterile. Accordingly, sterility is considered to be inherent characteristic of the container in Crippa.

**18. Claims 25-27 are rejected under 35 U.S.C. § 102(b) as being anticipated by Onishi (USP 4,294,372).**

The patent to Onishi discloses a walled container in Fig. 2 comprising a first chamber A and a second chamber B; a bridge 21a; a removable lid 23 or 25; and access ports 22 and 24.

*maintain*

**19. Claims 33, 34, 35, and 37 are rejected under 35 U.S.C. § 102(b) as being anticipated by Onishi (USP 4,294,372).**

The patent to Onishi discloses a rigid walled container of a suitable material (Col. 3, lines 36-39) in Fig. 2 comprising a first chamber A and a second chamber B; a

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bridge 21a; a removable lid 23 or 25; access ports 22 and 24; the bridge 21a being formed at the tops of the adjacent sidewalls of the chambers (Fig. 2).

\* \* \*

With regard to the above rejections, the operational and functional language of the claims (e.g., "effective to removably receive the container and position the container in one or more predetermined positions" (claim 22 - although this language is met by Raccuglia et al.) or "such that a substance can be transferred from the first chamber to the second chamber while the container is positioned at a predetermined angle" (claim 25), etc.) has been considered but fails to impart or invoke any means or structure to the *apparatus* claims which defines over the applied prior art.

With regard to the claim language "sterile", the examiner's position is that the term "sterile" does not impart any specific structure to the container, but is perhaps a product by process limitation as to the manner in which the container is made or the manner in which the container is packaged (e.g., hermetically sealed to maintain sterility). However, the pending claims are strictly apparatus claims drawn to a centrifuge and/or container and no particular process for manufacturing the sterile container, sterilizing the container, or packaging for the container is set forth that either imparts sterility to or maintains sterility of the container. Hence, it is not clear how the physical structure of the container changes to define over the prior art simply by labeling it "sterile". Since sterility itself is not considered to impart any unique structural

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features to define over the applied prior art, and since several of the prior art devices can reasonably be considered inherently sterile, the rejections are maintained.

***Claim Rejections - 35 U.S.C. § 103***

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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22. **Claims 25, 26, 27, 28, and 29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Raccuglia et al. (USP 3,190,546) in view of Le Veen (USP 3,221,741).**

The patent to Raccuglia et al. discloses a system for processing fluids such as blood in Figs. 8-11 comprising a centrifuge 212 with a rotor 214; a walled container 110, 112 (Figs. 8-9) having a first chamber 114 and a second chamber 116; a bridge 166, 162, 141, 140, 168, 164, 153, 152 for transferring fluid between the chambers; a holder assembly (Fig. 11) comprising a pivotally mounted frame 216 attached to the centrifuge rotor 214 for removably receiving the container 110, 112 and for positioning the container in multiple positions as seen in the solid and phantom positions of Figure 10; lid portions 120, 122; and access port 118. Assuming, *arguendo*, that the container of Raccuglia et al. is not sterile, the patent to Le Veen teaches that it was common practice as of 1962 to process blood in sterile containers (Col. 1, lines 9-15 and lines 40-44). It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified the container of Raccuglia et al. such that it is sterile as taught by Le Veen for the purpose of rendering the container free of microorganisms which could contaminate the materials in the container. Furthermore, the court has held that "[t]he sterilization of containers, when desired, also involves nothing more than the ordinary skill of the art." *In re Piazze and Baxter*, 109 USPQ 34, (CCPA 1956).

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**23. Claims 25, 26, 27, 28, and 29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Raccuglia et al. (USP 3,190,546) in view of Weber et al. (USP 3,228,444).**

The patent to Raccuglia et al. discloses a system for processing fluids such as blood in Figs. 8-11 comprising a centrifuge 212 with a rotor 214; a walled container 110, 112 (Figs. 8-9) having a first chamber 114 and a second chamber 116; a bridge 166, 162, 141, 140, 168, 164, 153, 152 for transferring fluid between the chambers; a holder assembly (Fig. 11) comprising a pivotally mounted frame 216 attached to the centrifuge rotor 214 for removably receiving the container 110, 112 and for positioning the container in multiple positions as seen in the solid and phantom positions of Figure 10; lid portions 120, 122; and access port 118. Assuming, *arguendo*, that the container of Raccuglia et al. is not sterile, the patent to Weber et al. '444 discloses a container 10, 12 for medical fluids that is sterile. It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified the container of Raccuglia et al. such that it is sterile as taught by Weber et al. '444 for the purpose of eliminating the likelihood for bacteria, fungus, or other extraneous matter to collect in the container and contaminate the sample (Col. 2, lines 10-18). Furthermore, the court has held that "[t]he sterilization of containers, when desired, also involves nothing more than the ordinary skill of the art." *In re Piazze and Baxter*, supra.

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**24. Claims 25-27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Li (USP 5,503,284) in view of Weber et al. (USP 3,228,444).**

The patent to Li discloses a walled container 12 comprising a first chamber 16, 38 and a second chamber 40; a bridge 34 for transferring fluid between the chambers (Figs. 3-8); a removable lid C; and access port 26. Li does not explicitly disclose that the container is sterile. Assuming, *arguendo*, that the container of Li is not sterile, the patent to Weber et al. '444 discloses a container 10, 12 for medical fluids that is sterile. It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified the container of Li such that it is sterile as taught by Weber et al. '444 for the purpose of eliminating the likelihood for bacteria, fungus, or other extraneous matter to collect in the container and contaminate the sample (Col. 2, lines 10-18). Furthermore, the court has held that "[t]he sterilization of containers, when desired, also involves nothing more than the ordinary skill of the art." *In re Piazze and Baxter, supra.*

**25. Claims 25-27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over McFarland (USP 3,642,163) in view of Weber et al. (USP 3,228,444).**

The patent to McFarland discloses a walled container (Fig. 1) comprising a first chamber 12 and a second chamber 14; a bridge 32; a removable lid 18; and access port (proximate 22). McFarland does not explicitly disclose that the container is sterile. Assuming, *arguendo*, that the container of McFarland is not sterile, the

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patent to Weber et al. '444 discloses a container 10, 12 for medical fluids that is sterile. It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified the container of McFarland such that it is sterile as taught by Weber et al. '444 for the purpose of eliminating the likelihood for bacteria, fungus, or other extraneous matter to collect in the container and contaminate the sample (Col. 2, lines 10-18). Furthermore, the court has held that "[t]he sterilization of containers, when desired, also involves nothing more than the ordinary skill of the art."

*In re Piazze and Baxter*, supra.

<sup>maintain</sup>  
**26. Claims 33 and 36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over McFarland (USP 3,642,163) in view of Weber et al. (USP 3,228,444).**

The patent to McFarland discloses a walled container (Fig. 3) comprising a first chamber 12A and a second chamber 14A; a bridge 62; lid 66; access ports 70; and separation disks 38. McFarland does not explicitly disclose that the container is sterile. Assuming, *arguendo*, that the container of McFarland is not sterile, the patent to Weber et al. '444 discloses a container 10, 12 for medical fluids that is sterile. It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified the container of McFarland such that it is sterile as taught by Weber et al. '444 for the purpose of eliminating the likelihood for bacteria, fungus, or other extraneous matter to collect in the container and contaminate the

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sample (Col. 2, lines 10-18). Furthermore, the court has held that “[t]he sterilization of containers, when desired, also involves nothing more than the ordinary skill of the art.”

*In re Piazze and Baxter*, *supra*.

**27. Claims 25-27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Crippa (USP 4,026,433) in view of Weber et al. (USP 3,228,444).**

The patent to Crippa discloses a walled container comprising a first chamber 1 and a second chamber 7; a bridge 4 (Fig. 4); a removable lid 10; and access port (proximate 6). Crippa does not explicitly disclose that the container is sterile. Assuming, *arguendo*, that the container of Crippa is not sterile, the patent to Weber et al. '444 discloses a container 10, 12 for medical fluids that is sterile. It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified the container of Crippa such that it is sterile as taught by Weber et al. '444 for the purpose of eliminating the likelihood for bacteria, fungus, or other extraneous matter to collect in the container and contaminate the sample (Col. 2, lines 10-18). Furthermore, the court has held that “[t]he sterilization of containers, when desired, also involves nothing more than the ordinary skill of the art.” *In re Piazze and Baxter*, *supra*.

Maintain

**28. Claims 33 and 37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Crippa (USP 4,026,433) in view of Weber et al. (USP 3,228,444).**

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The patent to Crippa discloses a walled container comprising a first chamber 1 and a second chamber 7; a bridge 4 (Fig. 4); a lid 10; access ports (proximate 3 and 6); the bridge 4 being formed at the tops of the adjacent sidewalls of the chambers (Fig. 4). Crippa does not explicitly disclose that the container is sterile. Assuming, *arguendo*, that the container of Crippa is not sterile, the patent to Weber et al. '444 discloses a container 10, 12 for medical fluids that is sterile. It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified the container of Crippa such that it is sterile as taught by Weber et al. '444 for the purpose of eliminating the likelihood for bacteria, fungus, or other extraneous matter to collect in the container and contaminate the sample (Col. 2, lines 10-18). Furthermore, the court has held that "[t]he sterilization of containers, when desired, also involves nothing more than the ordinary skill of the art." *In re Piazze and Baxter*, supra.

**29. Claims 25-27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Onishi (USP 4,294,372) in view of Weber et al. (USP 3,228,444).**

The patent to Onishi discloses a walled container in Fig. 2 comprising a first chamber A and a second chamber B; a bridge 21a; a removable lid 23 or 25; and access ports 22 and 24. Onishi does not explicitly disclose that the container is sterile. Assuming, *arguendo*, that the container of Onishi is not sterile, the patent to Weber et al. '444 discloses a container 10, 12 for medical fluids that is sterile. It would have

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been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified the container of Onishi such that it is sterile as taught by Weber et al. '444 for the purpose of eliminating the likelihood for bacteria, fungus, or other extraneous matter to collect in the container and contaminate the sample (Col. 2, lines 10-18). Furthermore, the court has held that "[t]he sterilization of containers, when desired, also involves nothing more than the ordinary skill of the art." *In re Piazze and Baxter, supra.*

30. **Claims 33, 34, 35, and 37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Onishi (USP 4,294,372) in view of Weber et al. (USP 3,228,444).**

The patent to Onishi discloses a rigid walled container of a suitable material (Col. 3, lines 36-39) in Fig. 2 comprising a first chamber A and a second chamber B; a bridge 21a; a removable lid 23 or 25; access ports 22 and 24; the bridge 21a being formed at the tops of the adjacent sidewalls of the chambers (Fig. 2). Onishi does not explicitly disclose that the container is sterile. Assuming, *arguendo*, that the container of Onishi is not sterile, the patent to Weber et al. '444 discloses a container 10, 12 for medical fluids that is sterile. It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified the container of Onishi such that it is sterile as taught by Weber et al. '444 for the purpose of eliminating the likelihood for bacteria, fungus, or other extraneous matter to collect in the container and contaminate the sample (Col. 2, lines 10-18). Furthermore, the court

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has held that “[t]he sterilization of containers, when desired, also involves nothing more than the ordinary skill of the art.” *In re Piazze and Baxter*, *supra*.

***Allowable Subject Matter***

31. Claim 30-32 would be allowable if rewritten to overcome the rejection under 35 U.S.C. § 251 and to include all of the limitations of the base claim and any intervening claims.

32. Claims 1-21 would be allowable if rewritten to overcome the rejection under 35 U.S.C. § 251.

***Response to Amendment***

33. Applicant's arguments filed 15 JUL 2002 have been fully considered but they are not deemed to be persuasive.

With regard to claim 22, the patent to Raccuglia et al. discloses a holder assembly (Fig. 11) comprising a pivotally mounted frame 216 attached to the centrifuge rotor 214 for removably receiving the container 110, 112 and for positioning the container in multiple positions as seen in the solid and phantom positions of Figure 10 which meets the limitations of the claim. Actually, the only structure recited is a “holder assembly” which is clearly present in Raccuglia et al.

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Applicant has requested motivation for making the containers sterile in the remarks filed 15 JUL 2002. In response, the examiner has provided such motivation as outlined in sections (20)-(30) above. Accordingly, in view of the teachings and suggestions of the prior art, it is respectfully not seen how the term "sterile" can viably constitute an a point of novelty or nonobviousness.

***Conclusion***

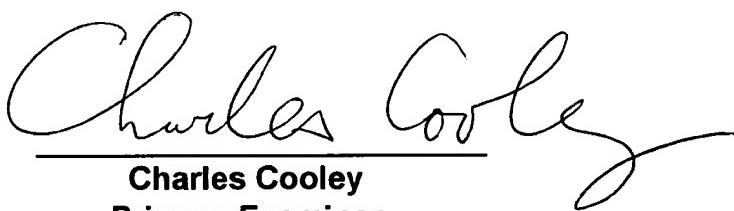
34. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The cited prior art discloses sterile containers.

35. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Charles Cooley whose telephone number is ☎ (703) 308-0112.

36. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1700 receptionist whose telephone number is ☎ (703) 308-0651.

Dated: 26 July 2002

  
\_\_\_\_\_  
**Charles Cooley**  
**Primary Examiner**  
**Art Unit 1723**